

REMARKS

A check in the amount of \$210 for the fee for a two-month extension of time is included with this response. Any fees that may be due in connection with filing this paper, or during the entire pendency of this application, may be charged to Deposit Account No. 50-1213. If a Petition for extension of time is needed, this paper is to be considered such Petition.

Claims 1, 3-12, and 14-33 are pending in this application. Claims 1, 3, 5-7, 9, 10, 12, 14, 17, 18, 20, 21, 24-26 and 27-32 are amended herein. Claims 2 and 13 are cancelled without prejudice or disclaimer, and claim 33 is added.

Claim 1 is amended to further define the hydrostatic couple, where the hydrostatic pressure-modulating agent includes a hydrophilic **cross-linked** polymer, and the agent of interest is released at a rate that is substantially concentration independent. Support for these amendments may be throughout the specification (for example, see page 19, line 18 to page 20, line 30, and page 26, lines 29-31).

Claims 3, 5-7, 9, 10, 14, 18, 20, 24, 25, and 27-32 are amended to change claim dependencies and to provide proper antecedent basis for various terms. Claim 12 is amended to include the subject matter of claim 13. Claims 12, 17, 21 and 26 are amended to correct spelling and formatting errors. The term "polyglycan" in claim 17 has been replaced with the term -polyglucan-, and the term "pullman" in claim 17 has been replaced with the term -pullulan-. Support for these amendments is provided throughout the specification (for example, see page 18, lines 1-2; and page 19, lines 1-3). Claim 18 is amended to specify that the hydrostatic pressure modulating agent of claim 1 includes a homopolymer of cross-linked N-vinyl-2-pyrrolidone. New claim 33 finds support throughout the disclosure, for example on page 16, line 10 to page 20, line 30.

Therefore, no new matter is added nor are any amendments made to change the scope of the claims. The amendments should place the claims and the application into condition for allowance.

U.S.S.N. 10/006,740
MacGregor
AMENDMENT

Priority Claim

The Examiner alleges that the present application is not entitled to the benefit of an earlier filing date under 35 U.S.C. § 119(e), because the provisional application upon which priority was based allegedly was filed greater than one year before the filing date of the present application. Applicant respectfully disagrees. As indicated on the filing receipt of the present application, the provisional application upon which priority was based was filed on December 5, 2000, exactly one year before the filing date of the present application. The last day of pendency of the provisional application under 35 U.S.C. § 119(e)(1) was December 5, 2001. The filing receipt reflects that the instant application received a filing date of December 5, 2001. Hence, applicant complied with the conditions for receiving the benefit of the earlier filing date. The present application is therefore entitled to the benefit of the earlier filing date of December 5, 2000, under 35 U.S.C. 119(e).

REJECTION OF CLAIMS 14-16 AND 18 UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 14-16 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being vague and indefinite because of the use of the term "CARBOPOL®". Claim 14 is amended herein to specify that the acrylic-acid polymer of claim 1 is an acrylic-acid polymer cross-linked with allylsucrose or allylpentaerythritol. It is respectfully submitted that this objection is obviated by the amendment of claim 14 herein.

Claim 18 is rejected under 35 U.S.C. § 112, second paragraph, for allegedly being vague and indefinite because of the use of the term "POLYPLASDONE®". Claim 18 is amended herein to specify that the hydrostatic pressure modulating agent of claim 1 comprises a homopolymer of cross-linked N-vinyl-2-pyrrolidone. It is respectfully submitted that this objection is obviated by the amendment of claim 14 herein.

In light of the above, the Examiner is respectfully requested to reconsider and withdraw the claim rejections against claims 14-16 and 18.

U.S.S.N. 10/006,740
MacGregor
AMENDMENT

REJECTION OF CLAIMS 1-3, 5, 13 AND 24 UNDER 35 U.S.C. §102(b)

Claims 1-3, 5, 13 and 24 are rejected under 35 U.S.C. § 102(b) as anticipated by Fritsch *et al.* (U.S. 5,213,794) because Fritsch *et al.* allegedly discloses every element of the delivery system claimed in claims 1-3, 5, 13 and 24. The Examiner alleges that Fritsch *et al.* discloses a tablet formulation that includes polyacrylic acid/methacrylate copolymer and polyvinylpyrrolidone and alleges that the combination of polyvinylpyrrolidone and the acrylate polymer is equivalent to the hydrostatic couple of the instant claims.

This rejection is respectfully traversed.

RELEVANT LAW

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990), *In re Bond*, 15 USPQ 1566 (Fed. Cir. 1990), *Soundsciber Corp. v. U.S.*, 360 F.2d 954, 148 USPQ 298, 301, adopted 149 USPQ 640 (Ct. Cl.) 1966. See, also, *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir.), *cert. denied*, 110 S.Ct. 154 (1989). "[A]ll limitations in the claims must be found in the reference, since the claims measure the invention". *In re Lang*, 644 F.2d 856, 862, 209 USPQ 288, 293 (CCPA 1981). Moreover, it is incumbent on Examiner to identify wherein each and every facet of the claimed invention is disclosed in the reference. *Lindemann Maschinen-fabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Further, the reference must describe the invention as claimed sufficiently to have placed a person of ordinary skill in the art in possession of the invention. *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

THE CLAIMS

Claim 1 is directed to a hydrostatic delivery system that includes a hydrostatic couple and an agent of interest, where the hydrostatic couple includes one or more than one, hydrodynamic fluid-imbibing polymer, and one or more than one, hydrostatic pressure-modulating agent, where the hydrostatic pressure-modulating agent includes a hydrophilic cross-linked polymer, and where the agent of interest is released at a rate that is substantially concentration independent.

U.S.S.N. 10/006,740
MacGregor
AMENDMENT

Claims 3, 5, 13 and 24 depend from claim 1 and are directed to various embodiments thereof.

Disclosure of Fritsch *et al.*

Fritsch *et al.* discloses a composition that includes an antacid, calcium polycarbophil (a calcium salt of polyacrylic acid crosslinked with divinyl glycol), and crospovidone (crosslinked polyvinylpyrrolidone; see Example 1, column 6, lines 19-54). Fritsch *et al.* discloses administering its compositions as chew tablets (see Column 5 line 33), and discloses that its compositions are characterized by dissolving rapidly (see Col 5 lines 27-34 and Col 6 lines 50-54). Fritsch *et al.* discloses that its compositions liberate granule particles that adhere to the gastric mucosa (e.g. Col 5 lines 10-16; Col 6 lines 52-53).

Differences between the claimed subject matter and the disclosure of Fritsch *et al.*

Fritsch *et al.* does not disclose a hydrostatic delivery system designed to produce a steady-state efflux, or a controlled release of the agent of interest over a period of time (see page 23, lines 9-24; Figures 2-6). Fritsch *et al.* does not disclose using a cross-linked hydrostatic pressure modulating agent. Fritsch *et al.* does not disclose a hydrostatic delivery system that releases an agent of interest at a rate that is substantially concentration independent (see for example page 26, lines 29-31).

Thus, Fritsch *et al.* does not disclose every element of claim 1 or claims dependent thereon. Therefore, because Fritsch *et al.* does not disclose all elements of the claimed subject matter of claim 1, Cook *et al.* does not anticipate any of claims 1-3, 5, 13 and 24.

REJECTION OF CLAIMS 1-3, 5, 7, 8, 11-15, 20, 21, 24, 26-29, 31 AND 32 UNDER 35 U.S.C. §102(b)

Claims 1-3, 5, 7, 8, 11-15, 20, 21, 24, 26-29, 31 and 32 are rejected under 35 U.S.C. § 102(b) as anticipated by Rork *et al.* (U.S. 5,582,838) because Rork *et al.* allegedly discloses every element of the delivery system claimed in claims 1-3, 5, 7, 8, 11-15, 20, 21, 24, 26-29, 31 and 32. The Examiner alleges that Rork *et al.* discloses a tablet formulation that includes an active ingredient,

U.S.S.N. 10/006,740
MacGregor
AMENDMENT

excipients such as polyvinylpyrrolidone and magnesium stearate, CARBOPOL polymer and carbonate, and alleges that the combination of polyvinylpyrrolidone and the CARBOPOL polymer is equivalent to the hydrostatic couple of the instant claims.

This rejection is respectfully traversed.

RELEVANT LAW

See related section above.

THE CLAIMS

See related section above.

Disclosure of Rork *et al.*

Rork *et al.* discloses a drug delivery device for the controlled *in situ* production and release of a suspension containing a beneficial agent, which includes a compressed core that includes at least two layers, at least one of which includes a polymer that upon hydration forms microscopic gelatinous beads, and a second layer that is a water insoluble, water impermeable polymeric coating that surrounds and adheres to the core (col. 4, lines 53-67). Rork *et al.* discloses a composition that includes nifedipine, CARBOPOL 974P (a carboxypoly-methylene prepared from acrylic acid crosslinked with allyl ethers of sucrose or pentaerythritol), and excipients, one of which disclosed in the long list is PROVIDONE K-90 (polyvinylpyrrolidone) (see Example 2, column 13, lines 18-59).

Differences between the claimed subject matter and the disclosure of Rork *et al.*

Rork *et al.* does not disclose a hydrostatic delivery system designed to release an agent of interest at a rate that is substantially concentration independent. Rork *et al.* does not disclose a crosslinked polyvinylpyrrolidone and thus does not disclose a hydrostatic pressure modulating agent.

Thus, Rork *et al.* does not disclose every element of claim 1 or claims dependent thereon. Therefore, because Fritsch *et al.* does not disclose all elements of the claimed subject matter of claim 1, Cook *et al.* does not anticipate any of claims 1-3, 5, 7, 8, 11-15, 20, 21, 24, 26-29, 31 and 32. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

U.S.S.N. 10/006,740
MacGregor
AMENDMENT

REJECTION OF CLAIMS 4, 6, 9, 10, 16 AND 19 UNDER 35 U.S.C. § 103(a)

Claims 4, 6, 9, 10, 16 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rork *et al.* (US 5,582,838) because the Examiner alleges that it would have been obvious to one of ordinary skill in the art to adjust the amounts of polymer to achieve the desired swelling for drug delivery or the amount of carbonate to include in the formulation or the particle size to be used in the formulation.

This rejection is respectfully traversed.

RELEVANT LAW

Under 35 U.S.C. § 103, in order to set forth a case of *prima facie* obviousness the differences between the teachings in the cited reference must be evaluated in terms of the whole invention, and the prior art must provide a teaching or suggestion to the person of ordinary skill in the art to have made the changes that would produce the claimed product. *See, e.g., Lindemann Maschinen-fabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462, 221 U.S.P.Q.2d 481, 488 (Fed. Cir. 1984). The mere fact that prior art may be modified to produce the claimed product does not make the modification obvious unless the prior art suggests the desirability of the modification. *In re Fritch*, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992); *see, also, In re Papesh*, 315 F.2d 381, 137 U.S.P.Q. 43 (CCPA 1963).

In addition, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Further, that which is within the capabilities of one skilled in the art is not synonymous with that which is obvious. *Ex parte Gerlach*, 212 USPQ 471 (Bd. APP. 1980). Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981), but it cannot be established by combining the teachings of the prior art to produce the claimed subject matter, absent some teaching or suggestion supporting the combination

U.S.S.N. 10/006,740
MacGregor
AMENDMENT

(*ACS Hosp. Systems, Inc. v Montefiore Hosp.*, 732 F.2d 1572, 1577. 221 USPQ 329, 933 (Fed. Cir. 1984)). "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher" *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983).

THE CLAIMS

Claims 4, 6, 9, 10, 16 and 19 depend ultimately from claim 1, which is discussed in the related section above.

TEACHINGS OF THE CITED ART

Rork *et al.*

See related section above.

ANALYSIS

It is respectfully submitted that the Examiner has failed to set forth a case of *prima facie* obviousness for the following reasons.

- (1) There would have been no motivation to have modified the teachings of Rork *et al.***

The cited reference must provide a teaching or suggestion to the person of ordinary skill in the art to have made the changes that applicant has done that would produce the claimed product. Rork *et al.* does not teach or suggest a hydrostatic delivery system designed to release an agent of interest at a rate that is substantially concentration independent. Instead, Rork *et al.* teaches that it is the selection of the size and number of apertures through its water-impermeable coating, which subsequently expose the surface of the core to the environment, that determines release rate (col. 11, lines 52-55). There is no teaching or suggestion that a controlled release of an agent of interest could be achieved by eliminating the water impermeable coating of Rork *et al.*, nor is there any guidance for selecting a combination of ingredients that when combined in a drug delivery system release an agent of interest at a rate that is substantially concentration independent. Further, Rork *et al.* does not teach or suggest that

U.S.S.N. 10/006,740
MacGregor
AMENDMENT

cross-linked polyvinylpyrrolidone functions as a hydrostatic pressure modulating agent. Instead, Rork *et al.* teaches that polyvinylpyrrolidone can be used as a stabilizing agent or to aid in the production of tablets, and suggests that polyvinylpyrrolidone is equivalent to a long list of ingredients in this functionality, such as lactose, magnesium stearate, microcrystalline cellulose, starch, stearic acid, calcium phosphate, glycerol monostearate, sucrose, gelatin, methylcellulose, sodium carboxymethyl-cellulose, sorbitol, mannitol and polyethylene glycol. Rork *et al.* does not teach or suggest a crosslinked polyvinylpyrrolidone and provides no motivation for substituting a crosslinked polyvinylpyrrolidone for any ingredient in its formulation, nor suggest any desirability of such a modification.

(2) Notwithstanding the lack of motivation, modification of the teachings of Rork *et al.* does not result in the instantly claimed delivery system.

As discussed above in the traverse of the rejection under §102(b), Rork *et al.* does not teach or suggest a hydrostatic couple as instantly claimed that includes an active ingredient, a hydrodynamic fluid-imbibing polymer (e.g. CARBOPOL), and a crosslinked polyvinylpyrrolidone (a hydrostatic pressure modulating agent) from which an agent of interest is released at a rate that is substantially concentration independent. Rork *et al.* does not teach or suggest a crosslinked polyvinylpyrrolidone. Rork *et al.* does not teach or suggest a hydrostatic pressure modulating agent. Rork *et al.* does not teach or suggest a composition that releases an agent of interest at a rate that is substantially concentration independent. Thus, Rork *et al.* does not teach or suggest every element of the subject matter of claim 1. Applicant respectfully submits that claims 4, 6, 9, 10, 16 and 19 depend from claim 1 and therefore include the limitations thereof. Therefore, Rork *et al.* does not teach or suggest every element of the subject matter of claims 4, 6, 9, 10, 16 and 19.

It is respectfully submitted that the Office Action does not set forth a case of *prima facie* obviousness. The Examiner has not shown that the reference teaches or suggests to the person of ordinary skill in the art to make the changes that would produce the claimed subject matter, nor that such modification would result in all the elements of the claimed subject matter. The Examiner is

U.S.S.N. 10/006,740
MacGregor
AMENDMENT

respectfully requested to reconsider and withdraw the rejection under 35 U.S.C.
§103(a) against claims 4, 6, 9, 10, 16 and 19.

* * *

In view of the amendments and remarks herein, reconsideration and
allowance of the application are respectfully requested.

Respectfully submitted,
HELLER EHRMAN WHITE & MCAULIFFE LLP

By: _____

Stephanie L. Seidman
Registration No. 33, 779

Attorney Docket No. 23936-0176
Address all correspondence to:
Stephanie L. Seidman, Esq.
HELLER EHRMAN WHITE & MCAULIFFE LLP
4350 La Jolla Village Drive
San Diego, CA 92122-1246
Telephone: 858 450-8400
Facsimile: 858 587-5360
e-mail: sseidman@HEWM.com